



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:  
Commissioner for Patents, P.O. Box 1450  
Alexandria, VA 22313 on April 29, 2004.

INFORMATION DISCLOSURE  
STATEMENT

Examining Group 1646

Patent Application

Docket No. GJE04.FD1

Serial No. 10/635,924

Doran R. Pace  
Doran R. Pace, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1646  
Applicant : Kim Sze Tan  
Serial No. : 10/635,924  
Filed : August 5, 2003  
Conf. No. : 1060  
For : High Affinity Humanized Monoclonal Antibodies

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §§1.97 and 1.98, Applicant would like to bring to the attention of the Examiner, the references cited in the following patent applications:

U.S. Serial No. 08/108,728, filed September 1, 1993, now abandoned, and

U.S. Serial No. 08/425,682, filed April 18, 1995, now abandoned.

The subject application, Serial No. 10/635,924, claims the benefit under 35 USC §120 of the filing date of the parent patent applications referred to above. Applicant respectfully requests that the copies of references supplied in the Information Disclosure Statements (IDS) of the parent applications, as well as references cited during the prosecution thereof, be made of record in the 10/635,924 application. As copies of the references filed in the parent applications, and cited on the attached form PTO/SB/08, can be found in the parent casefiles, copies of those references are not provided herewith.

Applicant has also listed on form PTO/SB/08 several references which have not been considered in the parent applications. A copy of the references are enclosed with this IDS. Applicant respectfully requests that these references be made of record and considered in the examination of the subject application.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statements.

Respectfully submitted,



Doran R. Pace  
Patent Attorney  
Registration No. 38,261  
Phone No.: 352-375-8100  
Fax No.: 352-372-5800  
Address: 2421 N.W. 41st Street, Suite A-1  
Gainesville, FL 32606-6669

DRP/sl

Attachment: Form PTO/SB/08



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/635,924
Filing Date	August 5, 2003
First Named Inventor	Kim Sze Tan
Art Unit	1646
Examiner Name	
Attorney Docket Number	GJE04.FD1

Sheet 1 of 3

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	F1	WO 91/09966 A1	07-11-1991	Ortho Pharmaceutical Corporation	All	
	F2	WO 91/09967	07-11-1991	Celltech Limited	All	
	F3					
	F4					
	F5					
	F6					
	F7					

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/635,924	
			Filing Date	August 5, 2003	
			First Named Inventor	Kim Sze Tan	
			Group Art Unit	1646	
			Examiner Name		
Sheet	2	of	3	Attorney Docket Number	GJE04.FD1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	TERASHIMA, M. <i>et al.</i> "Production Of Human-Human Hybridomas Secreting Antibody To Sheep Erythrocytes After In Vitro Immunization Of Peripheral Blood Lymphocytes," <i>Immunology Letters</i> , 1987, pp. 89-93, Vol. 15.	
	R2	TERASHIMA, M. <i>et al.</i> "A Protective Human Monoclonal Antibody Directed To The Outer Core Region Of Pseudomonas Aeruginosa Lipopolysaccharide," <i>Infection and Immunity</i> , 1991, pp. 1-6, Vol. 59, No. 1.	
	R3	KOMORI, S. <i>et al.</i> "Production Of Heavy-Chain Class-Switch Variants Of Human Monoclonal Antibody By Recombinant DNA Technology," <i>Clin. Exp. Immunol.</i> , 1988, pp. 508-516, Vol. 71.	
	R4	OI, T.L. <i>et al.</i> "Immunoglobulin Gene Expression In Transformed Lymphoid Cells," <i>Proc. Natl. Acad. Sci. USA</i> , 1983, pp. 825-829, Vol. 80.	
	R5	NEUBERGER, M.S. "Making Novel Antibodies by Expressing Transfected Immunoglobulin Genes," <i>TIBS</i> , 1985, pp. 347-349, Vol. 10.	
	R6	RAYBOULD, T.J.G. <i>et al.</i> "Production of Stable Rabbit-Mouse Hybridomas That Secrete Rabbit mAb of Defined Specificity", <i>Science</i> , 1988, pp. 1788-1790, Vol. 240.	
	R7	GROVES, D.J. <i>et al.</i> "A Bovine Monoclonal Antibody to Oestrone/Oestradiol Prepared by a (Murine X Bovine) X Bovine Interspecies Fusion", <i>Veterinary Immunology and Immunopathology</i> , 1988, pp. 95-101, Vol. 18.	
	R8	GROVES, D.J. <i>et al.</i> "The Preparation of an Ovine Monoclonal Antibody to Progesterone", <i>Journal of Endocrinology</i> , 1990, pp. 217-222, Vol. 126.	
	R9	GROVES, D.J. <i>et al.</i> "The Preparation of a Bovine Monoclonal Antibody to Testosterone Interspecies Fusion", <i>Res. Vet. Sci.</i> , 1987, pp. 253-256, Vol. 43.	
	R10	FLYNN, J.N. <i>et al.</i> "Analysis if Immune Responses in the Sheep to Synthetic Peptides of Foot-and-Mouth Disease Virus Using Ovine Polyclonal and Monoclonal Antibodies", <i>Immunology</i> , 1990, pp. 1-7, Vol. 69.	
	R11	WINTER, G. <i>et al.</i> "Man-made Antibodies", 1991, <i>Nature</i> , pp. 293-299, Vol. 349.	
	R12	QUEEN, C. <i>et al.</i> "A Humanized Antibody that Binds to the Interleukin 2 Receptor", <i>Proc. Natl. Acad. Sci. USA</i> , 1989, pp. 10029-10033, Vol. 86.	
	R13	KUZMANOFF, K.M. <i>et al.</i> "Isolation of Monoclonal Antibodies Monospecific for Bovine Alpha-Lactal-Bumin", <i>J. Dairy Sci.</i> , 1990, pp. 3077-3083, Vol. 73, No. 11.	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application-form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/635,924
Filing Date	August 5, 2003
First Named Inventor	Kim Sze Tan
Group Art Unit	1646
Examiner Name	
Attorney Docket Number	GJE04.FD1

Sheet	3	of	3
-------	---	----	---

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R14	WILLIAMS, D.J. <i>et al.</i> "Quantification of Bovine Immunoglobulin Isotypes and Allotypes Using Monoclonal Antibodies", <i>Vet. Immunol. Immunopathol.</i> , 1990, pp. 267-283, Vol. 24, No. 3.	
	R15	SMITH, T.W. "Review of Clinical Experience with Digoxin Immune Fab (ovine)", <i>Am. J. Emerg. Med.</i> , 1991, pp. 1-6, Vol. 9, No. 2, Supp. 1.	
	R16	GROVES, D.J. <i>et al.</i> "The Production and Application of Non-Rodent Monoclonal Antibodies in Veterinary Science", <i>Veterinary Immunology and Immunopathology</i> , 1989, pp. 1-14, Vol. 23.	
	R17	EHRILICH, P.H. <i>et al.</i> "Human and Primate Monoclonal Antibodies for in Vivo Therapy", <i>Clin. Chem.</i> , 1988, pp. 1681-1688, Vol. 34, No. 9.	
	R18	STEWART, M.W. "Factors Affecting Antibody Affinity" <u>Antibody Affinity</u> , 1983, pp. 115-122, CRC Press, Inc., Boca Raton, FL.	
	R19	STEWART, M.W. "The Biological Significance of Antibody Affinity", <u>Antibody Affinity: Thermodynamic Aspects and Biological Significance</u> , 1983, pp. 145-153, CRC Press, Inc., Boca Raton, FL.	
	R20	MAYFORTH, R.D. <u>Designing Antibodies</u> , 1993, pp. 59-60, Academic Press, Inc., San Diego, CA.	
	R21	RAINEY, P.M. "Effects of Digoxin Immune Fab (ovine) on Digoxin Immunoassays", <i>Amer. J. Clin. Pathol.</i> , 1989, pp. 779-786, Vol. 92, No. 6.	
	R22	MORRISON, S.L. "Transfectomas Provide Novel Chimeric Antibodies", <i>Science</i> , 1985, pp. 1202-1207, Vol. 229.	
	R23	WALDMANN, T.A. "Monoclonal Antibodies in Diagnosis and Therapy", <i>Science</i> , 1991, pp. 1657-1662, Vol. 252.	
	R24	GROVES, D.J. <i>et al.</i> "Production of an Ovine Monoclonal Antibody to Testosterone by an Interspecies Fusion", <i>Hybridoma</i> , 1987, pp. 71-76, Vol. 6, No. 1.	
	R25	SEVIER, E.D. <i>et al.</i> "Monoclonal Antibodies in Clinical Immunology", <i>Clin. Chem.</i> , 1981, pp. 1797-1806, Vol. 27, No. 11.	
	R26	HARLOW, E. <i>et al.</i> "Antibody-Antigen Interactions", <u>Antibodies: A Laboratory Manual</u> , 1988, pp. 23-33, Cold Spring Harbor Laboratory.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.